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EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT PAPER NUMBER

1654

DATE MAILED: 05/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/622,977	Applicant(s) VIAMONTE ET AL.	
	Examiner Christopher R. Tate	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>0703</u> . | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

Claims 1-17 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3, 10, and 12 are rendered vague and indefinite by the phrase "an [or "said] aloe or aloe derivative component". The term derivative therein is unclear and, further, the metes and bounds are not adequately delineated. For example, a derivative reads upon essentially anything derived from aloe including water, small molecules, atoms (e.g., carbon atoms) and/or inactive tissue/cells/compounds/agents therefrom. It is, therefore, suggested that the term "derivative" be omitted from this phrase to overcome this rejection.

Claims 2 and 11 each recite the limitation "said aloe component". There is insufficient antecedent basis for this limitation in these claims because both of these claims depend from claims which recite "aloe derivative component" (not "aloe component").

Claim 16 is rendered vague and indefinite by the term "ok" which appears after the phrase "pure aloe gel 5-10%". It is unclear as to what this term is attempting to define - is this perhaps a typo?

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

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Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-17 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-17 of copending Application No. 10/623,816. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thornton*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,296,882 in view of Danieli (US 6,488,948), Shupe et al. (US 6,290,964), and Doi et al. (US 5,908,865).

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The claimed invention of '882 and the instantly claimed invention are both drawn to a non-toxic mucosal disinfectant for topical application in the nose comprising the same or similar amounts of isopropyl alcohol, sesame oil, and lemon oil. Further, please note that the instantly recited amounts of these components are each within (and, thus, encompassed by) the amounts claimed in '882. The claimed topical disinfectant composition of '882 does not teach the inclusion of aloe (or aloe component), nor other claimed components - i.e., grapefruit seed extract or chlorhexidine gluconate.

Danieli teaches a topical disinfectant/antiseptic composition which Danieli discloses may beneficially include aloe vera extract and/or aloe vera gel to act as moisturizer (which is notoriously well recognized in the art), and grapefruit seed extract to act as an antibacterial therein (see, e.g., col 3, line 25 - col 4, line 12, and claims) - please note that such an aloe vera extract/gel would intrinsically contain the claimed naturally occurring aloe components therein. In addition, Shupe et al. teach a disinfectant/antimicrobial composition comprising aloe vera (and components thereof) as the primary antimicrobial agent ingredient therein (see entire document). Shupe et al. further disclose that the aloe components aloin and emodin showed antimicrobial activity, and that aloe vera is well known in the art to promote skin healing as well as to act as an antimicrobial/ antibacterial agent against infectious diseases (see entire document including abstract; cols 1-2; col 3, lines 62-64; col 4, lines 55-62; col 6, line 60-col 7, line 3).

Doi et al. beneficially disclose that chlorhexidine gluconate is well known in the art to be widely used as an effective topical disinfectant, including within nose sprays (see, e.g., col 1, lines 11-22).

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It would clearly have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the ingredients claimed within the topical disinfectant composition of '882 with the other conventionally employed topical ingredients instantly claimed for their known benefit based upon the teachings provided by the secondary references, including (as advantageously taught by the secondary references above) that each of these other ingredients is well known in the art to be useful for the same purpose (e.g., for use as effective topical agents including as disinfectant/antiseptic agents, as well as for aloe - as an effective topical skin moisturizer/healing agent) and for the following reason. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Sussman, 1943 C.D. 518; In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). The adjustment of particular conventional working conditions (e.g., determining a result-effective amount of aloe, grapefruit seed extract, chlorhexidine gluconate, and/or other claimed topical ingredient therein) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the claimed invention as a whole is *prima facie* obvious, especially in the absence of evidence to the contrary.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being obvious over Viamonte, Jr. (US 6,296,882) in view of Danieli (US 6,488,948), Shupe et al. (US 6,290,964), and Doi et al. (US 5,908,865).

Viamonte, Jr. teaches a non-toxic mucosal disinfectant for topical application in the nose comprising the same or similar amounts of isopropyl alcohol, sesame oil, and lemon oil (and/or lemon essence) as instantly claimed (see entire document including claims). Viamonte, Jr. does not expressly teach the inclusion of aloe (or aloe component), nor other claimed components - i.e., grapefruit seed extract or chlorhexidine gluconate within the disinfectant composition.

Danieli teaches a topical disinfectant/antiseptic composition which Danieli discloses may beneficially include aloe vera extract and/or aloe vera gel to act as moisturizer (which is notoriously well recognized in the art), and grapefruit seed extract to act as an antibacterial therein (see, e.g., col 3, line 25 - col 4, line 12, and claims) - please note that such an aloe vera extract/gel would intrinsically contain the claimed naturally occurring aloe components therein.

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In addition, Shupe et al. teach a disinfectant/antimicrobial composition comprising aloe vera (and components thereof) as the primary antimicrobial agent ingredient therein (see entire document). Shupe et al. further disclose that the aloe components aloin and emodin showed antimicrobial activity, and that aloe vera is well known in the art to promote skin healing as well as to act as an antimicrobial/antibacterial agent against infectious diseases (see entire document including abstract; cols 1-2; col 3, lines 62-64; col 4, lines 55-62; col 6, line 60-col 7, line 3).

Doi et al. beneficially disclose that chlorhexidine gluconate is well known in the art to be widely used as an effective topical disinfectant, including within nose sprays (see, e.g., col 1, lines 11-22).

It would clearly have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the ingredients d within the topical disinfectant composition taught by Viamonte, Jr. with the other conventionally employed topical ingredients instantly claimed for their known benefit based upon the teachings provided by the secondary references, including (as advantageously taught by the secondary references above) that each of these other ingredients is well known in the art to be useful for the same purpose (e.g., for use as effective topical agents including as disinfectant/antiseptic agents, as well as for aloe - as an effective topical skin moisturizer/healing agent) and for the following reason. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Sussman, 1943 C.D. 518; In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ

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423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).. The adjustment of particular conventional working conditions (e.g., determining a result-effective amount of aloe, grapefruit seed extract, chlorhexidine gluconate, and/or other claimed topical ingredient therein) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Christopher R. Tate
Primary Examiner
Art Unit 1654